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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,582	08/07/2001	Robert A. Beach	Q105	2712
7590 12/08/2003				
Daniel L. Dawes, Esq. MYERS, DAWES & ANDRAS LLP 5252 Kenilworth Drive Huntington Beach, CA 92649			EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,582

Applicant(s)

BEACH ET AL.

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of group I, claims 1 – 19 in the response submitted 10/16/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure is objected to because of the following informalities: The blank spaces referring to the serial no. and filing dates of the copending applications on pages 5 and 7 should be corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said plurality of micropumps" in line 3. There is insufficient antecedent basis for this limitation in the claim.

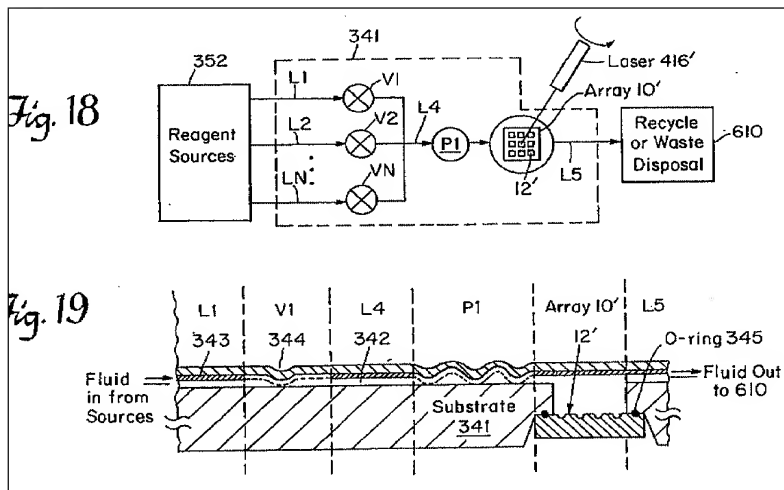
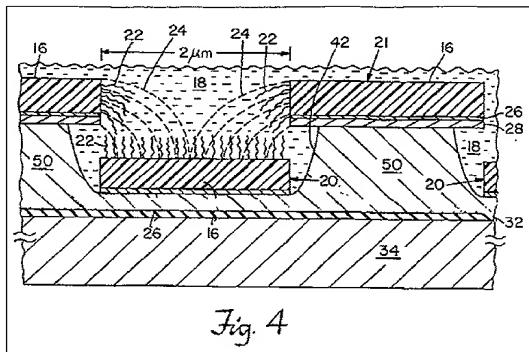
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 3, 6 – 8, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis *et al.* (U.S. Pat. No. 5,653,939 A). Regarding claims 1 – 3, Hollis *et al.* teach an apparatus comprising: an integrated microfluidic peristaltic pump (P1); a plurality of analysis chambers (wells 42 formed in each test site 12' contained in array 10) in communication with the pump; and a plurality of analysis devices (*i.e.*, a micromechanical resonator, surface acoustic or electromagnetic wave detector, or a monolithically integrated charge-coupled device (CCD), *etc.*) which test a fluid contained within the analysis chambers for an analyte (see col. 4, line 15 – col. 15, line 51; figures 1 – 6, 18 & 19). Regarding claims 2 and 3, Hollis *et al.* do teach that the wells are rinsed or flushed during operation (see col. 6, lines 56 – 59).



Furthermore regarding claims 2 and 3, these claims are directed to an apparatus statutory class of invention. Therefore, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus. These claims

recite how the pump apparatus is to be operated, which do not impart any limitations to define the structure of the apparatus being claimed. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Regarding claim 6, Hollis *et al.* teach that the microfluidic flow system comprising: an electro-deformable membrane (*e.g.*, membrane actuator layer 344 comprising a PVDF polymer); a substrate (341) disposed below the membrane and coupled thereto, wherein a microchannel (*e.g.*, 342 & 343), which has a longitudinal axis, is defined between the membrane and the substrate; and a metal electrode structure disposed on at least one side of the membrane along side of the microchannel (see col. 14, lines 49 – 67; col. 15, lines 1 – 14; figure 19). Regarding claim 7, as shown in figure 19, the electro-deformable membrane (344) is bowed to form a curvature having a symmetrical axis in the direction of the longitudinal axis of the microchannel (342 & 343). Regarding claim 8, Hollis *et al.* teach that the membrane actuator membrane layer (344) is deformed electrostatically due to the application of DC voltage (see col. 15, lines 2 – 6).

Regarding claim 18, Hollis *et al.* anticipate the incorporation of an integrated control circuit, such as on on-chip microprocessor controller, coupled to the pump apparatus for controlling fluid flow and access to each test site (see col. 20, lines 10 – 16).

Regarding claim 19, Hollis *et al.* teach that standard photolithography techniques are used in fabricating the disclosed apparatus. This claim is considered a product-by-process claim. The Courts have held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. See *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). With respect to claim 1, Hollis *et al.* teach the apparatus structure recited therein, as discussed above. The patentability of a product, or apparatus, does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process (see MPEP § 2113).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis *et al.* in view of Thomas *et al.* (U.S. Pat. No. 6,444,474 B1). Regarding claim 4, Hollis *et al.* do not specifically teach the incorporation of an integrated light emitting diode (LED). Hollis *et al.* do teach the incorporation of an integrated optical detector, such as a monolithically integrated charge-coupled device (CCD) (see col. 8, lines 59 – 67). Hollis *et al.* do teach the incorporation of a laser light source (416') for laser scanning of the test sites (see col. 14, lines 33 – 50). Thomas *et al.* do teach the use of LED and laser diode light sources with a microfluidic analysis system (see col. 16, lines 36 – 45). Therefore, a person of ordinary skill in the art, as evidenced by Thomas *et al.*, would have recognized the suitability of incorporating an integrated LED with a microfluidic analysis system for the same intended purpose of facilitating effective sample processing and analysis (see MPEP § 2144.07). Furthermore, these light emission systems are considered functional equivalents clearly recognized in the prior art (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an integrated LED, as taught by Thomas *et al.*, with the analytical detection system, as taught by Hollis *et al.*, in order to facilitate effective sample processing and analysis. Regarding claim 5, the recitation that the integrated LED and integrated optical detector are tuned to an optical absorption line of an analyte is considered a functional limitation. In a claim drawn to an apparatus statutory class of invention, a functional limitation may not be divorced from any specific structure or specific composition. A functional

limitation is an attempt to define an apparatus by what it does, rather than by what it is, *as evidenced by its specific structure* (emphasis added) (see MPEP § 2173.05(g)). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); & *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis *et al.* in view of Mouri (U.S. Pat. No. 6,495,852 B1). Hollis *et al.* do not specifically teach the incorporation an electrodeformable membrane comprised of p-type GaN. Hollis *et al.* do teach that the membrane actuator layer (344) comprising the electrodeformable membrane is comprised of a piezoelectric material (see col. 14, lines 57 – 66). Mouri does teach that gallium nitride materials generally have a large piezoelectric constant (see col. 4, lines 1 – 63). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an electrodeformable membrane comprised of p-type GaN, since the Courts have held that the selection of a known material based upon its suitability for the intended use is within the ambit of a person of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960).

Allowable Subject Matter

Claims 11 – 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 11 – 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art neither teach or fairly suggest that the apparatus further comprise two opposing pillars disposed on the substrate between the substrate and the membrane generally aligned in the direction of the longitudinal axis. Furthermore, the cited prior art neither teach or fairly suggest that the electrode structure further comprises two opposing electrode substructures extending parallel to the microchannel.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Parce teaches a micropump for a microfluidic system. Zanzucchi *et al.* teach a liquid distribution system, which utilizes a peristaltic pump apparatus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700